UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

BETTY J. STEINMAN and
RICHARD STEINMAN,[1]

Plaintiffs,

v.

DECISION AND ORDER
05-CV-774S

SPINAL CONCEPTS, INC.,[2]

Defendant.

I. INTRODUCTION

In this diversity action, Plaintiff Betty Steinman, claims that Defendant, Spinal Concepts, Inc. ("Spinal Concepts"), is strictly liable for its design and manufacture of an allegedly defective medical device, the SC-AcuFix Anterior Cervical Plate System ("AcuFix System"), which was surgically implanted in her spine. Steinman further claims that Spinal Concepts negligently designed the AcuFix System, failed to provide adequate warnings, and breached implied warranties. Jurisdiction is proper under 28 U.S.C. § 1332.[3]

Three motions are presently before this Court: (1) Spinal Concepts' motion to exclude the testimony of both Steinman's expert witness and her treating physician (Docket No. 72); (2) Spinal Concepts' motion for summary judgment (Docket No. 46); and (3) Steinman's motion for summary judgment. (Docket No. 64.) For the following reasons,

[1]Betty Steinman's husband, Richard Steinman, brings a derivative loss of consortium claim.

[2]Spinal Concepts, Inc. is now known as Abbott Spine, Inc. For the purposes of clarity and consistency, this Court will only use the name "Spinal Concepts."

[3]Plaintiffs are residents of the State of New York, County of Niagara. (Complaint ¶ 1; Docket 1-4, Exhibit B.) Defendant is a Delaware corporation with its principle place of business in Texas. (Notice of Removal; Docket 1.) Plaintiff has demanded over $75,000. (Docket No. 1, Exhibit D.)

Spinal Concepts motion to exclude is denied, and its motion for summary judgment is granted in part and denied in part. Further, Steinman's motion for summary judgment is denied.

II. BACKGROUND

Much of the relevant background is undisputed. On December 18, 2000, Steinman, in the course of her employment as a home-healthcare worker, slipped and fell as she was getting out of her car. (Plaintiff's Statement of Undisputed Facts ¶¶ 1-2; Docket No. 65.[4]) When several treatments proved unsuccessful, she was referred to Dr. William Capicotto, who diagnosed her with a cervical herniation in her spine at her C5-C6 vertebrae, and severe injuries to her C6-C7 vertebrae.[5] (Id. ¶¶ 7-12.) Dr. Capicotto recommended surgery, where he would attempt to fuse the C5 to the C7 vertebra with the use of the AcuFix system. The system consists of a plate and four screws that are specifically designed for this type of procedure. (Id. ¶¶ 12, 17-18, 37.) Performing the surgery on May 3, 2002, Dr. Capicotto made an incision in the front of Steinman's neck and removed her herniated discs and the C6 vertebra. (Capicotto Declaration ¶ 18; Docket No. 69.) He then inserted a piece of bone into the space created by the removal of the C6 and connected the C5 to the C7 vertebra with the AcuFix plate and screws, intending that the C5 would eventually fuse to the C7. (Id.) According to Dr. Capicotto, this is a routine procedure. (Id. ¶ 19.)

Initially, the surgery appeared to be a success, alleviating Steinman's pain.

[4]This Court has accepted facts included in Plaintiff's and Defendant's Statement of Facts to the extent that they have not controverted each other's statements. See Local Rule 56(a)(2) (statements of material fact that are not specifically controverted by the non-moving party are deemed admitted).

[5]The seven individual cervical vertebrae in the neck are commonly abbreviated C1 through C7.

(Plaintiff's Statement of Undisputed Facts ¶¶ 13, 20.) Steinman's X-rays in the months following the surgery also indicated that she was healing properly. (Id. ¶ 21-23.) At some point after an August 5, 2002 visit with Dr. Capicotto, however, Steinman began to experience a new, severe pain. (Id. ¶ 24.) She was not able to get an appointment until December. (Id. ¶ 26.) At that time, Dr. Capicotto took another set of X-rays, which revealed that the bottom two screws, those located in her C7 vertebra, had fractured. (Id. ¶ 28.) Steinman tried to live with the pain, but it ultimately became too much, and she decided to have surgery to remove the plate and broken screws. (Id. ¶ 30.) In the course of this surgery, Dr. Capicotto was able to remove the plate, two fully intact screws, and two fragmented screws. He decided to leave the remaining screw fragments in her C7 vertebra, instead of trying to dig them out. (Id. ¶ 32.)

Although her pain decreased after the second surgery, it did not subside entirely. (Id. ¶ 34.) On March 6, 2007, she underwent a third surgery on her spine, this one performed by Dr. Christopher Hamill.[6] This surgery did not fully alleviate Steinman's pain either, and she continues to experience a moderate amount of cervical pain to this day. (Id. ¶ 36.)

III. DISCUSSION

A. Motion to Exclude Plaintiff's Witnesses

Steinman has named Ronald Parrington, P.E., a metallurgical engineer, as her expert witness. In short, Spinal Concepts argues that Parrington's testimony is insufficiently reliable under Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow

[6]Dr. Capicotto treated Steinman only while her workers compensation case was pending, and by this point, her claim had been settled.

Pharm., Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed. 2d 469 (1993) because he has no education or training with respect to medical devices or biomechanics. Spinal Concepts also moves to exclude the testimony of Steinman's treating physician, Dr. Capicotto, arguing that his opinion is not based on scientific knowledge.

1. Legal Standard

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which reads:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The proponent of expert testimony has the burden of demonstrating by a preponderance of the evidence that the testimony is competent, relevant, and reliable. See Daubert, 509 U.S. at 592, n.10; Koppell v. New York State Bd. of Elections, 97 F. Supp. 2d 477, 479 (S.D.N.Y .2000); Bourjaily v. United States, 483 U.S. 171, 107 S.Ct. 2775, 97 L.Ed.2d 144 (1987)). If the expert is deemed competent (otherwise referred to as "qualified"), the trial court must then determine, pursuant to its "gatekeeping" function, whether the proffered expert testimony is "relevant" and "reliable." See Fed. R. Evid. 702 (Advisory Committee Notes, 2000 amendment) (noting that trial judges have "the responsibility of acting as gatekeepers to exclude unreliable expert testimony").

Evidence is relevant if the testimony tends to make the existence of any fact that is of consequence to the determination of the action more probable or less probable.

Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 264 (2d Cir. 2002). If the evidence is relevant, the trial court must then determine "whether the proffered testimony has a sufficiently reliable foundation to permit it to be considered" by the trier of fact. Id. at 265. Expert testimony may be considered reliable if: (1) the testimony is based on sufficient facts or data; (2) the expert's technique or methodology in reaching the conclusion is considered reliable; and (3) the expert has applied the methodology reliably to the facts of the case. Fed. R. Evid. 702. None of these factors are determinative. Id. (Advisory Committee Notes, 2000 amendments); see also Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150-51, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). Rather, district courts have broad discretion in deciding the admissibility of expert testimony. See United States v. Farhane, 634 F.3d 127, 158 (2d Cir. 2011) (citing Kumho, 526 U.S. at 152).

2. Ronald Parrington, P.E.

To support Steinman's contention that the product was defective, Steinman relies on the testimony of Ronald Parrington, a materials engineer specializing in failure analysis. Based on an examination of the metallurgical properties, and the frequency and spacing of stress marks in the screws, Parrington found that the screws withstood about 105,000 cycles,[7] or stresses, before failure. (Parrington Declaration ¶¶ 28-46; Docket 70.) Comparing this number to standards set out by the American Society for Testing and Materials ("ASTM"), he concluded that the screws suffered a premature failure.

Spinal Concepts does not dispute Parrington's qualifications regarding his expertise

[7]Both parties agree that one cycle can be analogized to the bending, then straightening, of a paperclip. (See James Freid Deposition, p. 50; Docket No. 68-13; Exhibit L; see also Parrington Declaration p. 94.)

in materials engineering, rather it asserts that he is not qualified to present his opinion on this matter because he has no background in medical science.

Parrington, however, does not purport to be an expert in medical device design. Rather, his testimony concentrates exclusively on reasons for the screws' fracture, and there is no dispute that this case revolves, almost entirely, around two broken screws. Parrington does not attempt to offer medical or biological opinions; instead he focuses on metal design and failure, his undisputed area of expertise as evidenced by his extensive education and experience in the field. (See Parrington Curriculum Vitae, Docket No. 70, Exhibit A.)

An expert "should not be required to satisfy an overly narrow test of his own qualifications." King v. Brandtjen & Kluge, Inc., No. 94 Civ. 4111, 2001 WL 1804345, *2 (W.D.N.Y. June 20, 2001). Nor does an expert's knowledge about a particular subject need be precisely informed about all the details of the issue raised in order to offer an opinion. Id. (citing Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799 (4th Cir. 1989)). Simply because this device was used in the medical field does not mandate an added level of expertise. To do so would impose an overly narrow test and hamper Steinman's ability to present her case. More importantly, it would impede the function of Rule 702: "to assist the trier of fact in understanding scientific, technical or other specialized knowledge." Steinman, relying on his background, experience, and education, offers an explanation of the screws' failure that may assist the trier of fact. Therefore, Spinal Concepts' motion is denied on this ground.

Spinal Concepts also claims that Parrington's testimony is inadmissable because the method he used to estimate the number of cycles that the screws withstood before

failure was unreliable. To reach his conclusion, Parrington counted the number of beach[8] and ratchet marks[9] on the screws' surface. (Parrington Declaration, ¶¶ 27-34.) He then examined the fatigue striations[10] and calculated the distance between each striation to determine the number of the cycles from crack initiation to ultimate failure. This methodology is recognized by ASM International[11] as a permissible measure of the cyclic loading necessary to cause the failure of a given material. ASM HANDBOOK,11 FAILURE ANALYSIS AND PREVENTION, 1066 (William T. Becker and Rosh J. Shirpley, eds. 2002). As such, Parrington based his conclusion on accepted and reasonable methodology. Further, only when there is "too great an analytical gap between the data and the opinion proffered should an expert's opinion be excluded." Gen. Elec. Co., v. Joiner, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). Here, Steinman has demonstrated that Parrington's methods and the data he gathered were sufficiently connected to his conclusion.

Because Parrington is sufficiently qualified to offer an opinion on metallurgical failure, he limits his testimony to this field, his methodology is not unreliable, and the issue

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[8]Beach marks represent the propagation of a crack through a material due to fatigue. They are typically found on service fractures where the part is loaded randomly, intermittently, or with periodic variations in mean stress or alternating stress. Glossary of Corrosion Related Terms, The Hendrix Group, Materials and Corrosion Engineers, http://hghouston.com/Resources/CorrosionGlossary/B.aspx

[9]Ratchet marks are lines on a fatigue fracture surface that result from the intersection and connection of fatigue fractures propagating from multiple origins. Ratchet marks are parallel to the overall direction of crack propagation and are visible to the unaided eye or at low magnification. Glossary of Terms, T&C Euro Lab, Testing and Consulting, Failure Analysis, http://www.tec-eurolab.com/en/doc=33-7.aspx

[10]A striation is a fatigue fracture often observed in electron micrographs that indicates the position of the crack after each succeeding cycle of stress. Glossary of Terms, T&C Euro Lab, Testing and Consulting, Failure Analysis, http://www.tec-eurolab.com/en/doc-33-7.aspx

[11]ASM, now standing on its own, was previously an abbreviation for American Society of Metals. (Parrington Declaration p. 25.)

of metal failure is relevant, if not essential, to this litigation, Spinal Concepts' motion to exclude his testimony is denied.

3. William Capicotto, M.D.

Spinal Concepts first argues that the testimony of William Capicotto, Steinman's treating orthopedic surgeon, should be excluded because he was not disclosed as an expert witness and provided no written report of his opinion under Rule 26 of the Federal Rules of Civil Procedure.[12] But the plain language of this rule only requires a written report for "a witness retained or specially employed to provide expert testimony, or whose duties as a party's employee regularly involve the giving of expert testimony." Fed R. Civ. P. 26(a)(2)(B). As explained in the Advisory Committee Notes, this language excludes treating physicians: "A treating physician, for example, can be deposed or called to testify at trial without any requirement for a written report." Fed. R. Civ. P. 26(a)(2) (Advisory Committee's Notes, 1993 amendment); see also Salas v. United States, 165 F.R.D. 31, 33 (W.D.N.Y. 1995) ("[T]o the extent that a treating physician testifies only to the care and treatment of the patient, the physician is not considered to be a "specially employed" expert and is not subject to the written report requirements of Rule 26(a)(2)(B).") Dr. Capicotto has not been retained as an expert, nor has he been compensated. (Cummings Declaration ¶¶ 18-22.) Therefore, Steinman was not required to disclose him as an expert or provide

[12] Rule 26(a)(2)(A): "In addition to the disclosures required by Rule 26(a)(1), a party must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705."

a report of his findings. As a result, this Court will not preclude Dr. Capicotto's testimony on this ground.

Spinal Concepts next seeks to exclude Dr. Capicotto's testimony because his opinions are not based on scientific facts or data as required by Rule 702 of the Federal Rules of Evidence.

There is no bright-line rule that establishes whether a treating physician should be treated as either an expert or lay witness; instead, courts must look to the nature and extent of the physician's testimony. See Salas v. United States, 165 F.R.D. 31, 33 (W.D.N.Y. 1995); see also Peck v. Hudson City School Dist., 100 F. Supp. 2d 118, 121 (N.D.N.Y. 2000) (finding that only when treating physician's testimony goes beyond facts of patient's care and when the doctor is specifically retained to develop opinion testimony should the physician be considered an expert); In re Fosamax Prods. Liab. Litig., 647 F.Supp.2d 265 (S.D.N.Y. 2009) ("Often, the determination is based on the specific facts of the case and the content of the proffered testimony itself.")

Here, it appears that Spinal Concepts objects to a few lines in Dr. Capicotto's deposition. When asked by Spinal Concept's counsel whether he thought that the AcuFix System was defective, he responded, "I've had three negative experiences with screw breakage; so I fe[el] there's something about the product that is lacking." (Capicotto Deposition, pp. 180-81; Docket No. 48.)

To the extent that Dr. Capicotto will testify about any defects in the design or manufacture of the Acufix system, he is clearly not qualified. However, Dr. Capicotto does not proffer technical or medical explanations for the device's failure. Rather, his testimony at deposition concerned only his experiences with, observations, and personal knowledge

of the AcuFix product. This is within the realm of lay witness testimony:

> If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

Fed. R. Civ. P. 701.

The distinction between a lay witness' and an expert witness' opinion is that a lay witness provides an opinion "result[ing] from a process of reasoning familiar with everyday life," while an expert testimony "results from a process of reasoning which can be mastered only by specialists in the field." Fed. R. Evid. 701 (Advisory Committee Notes, 2000 amendment). Rendering a simple conclusion that a product may have a defect because one's experiences with that product have been negative requires no advanced degree or intensive study. It is a "process of reasoning familiar with everyday life." Id. While Dr. Capicotto's testimony may be attacked or objected to on other grounds, it is not objectionable under Rule 702 because his opinions are not scientific or technical. Consequently, Spinal Concepts' motion to exclude his testimony is denied.

B. Motions for Summary Judgment

Neither party disputes that the AcuFix screws broke, but both parties have moved for summary judgment. Simply put, Steinman contends that her pain and follow-up surgeries were the result of the fracture of the implanted screw and its defective design and/or manufacture. Defendants contend that screws broke only because the intended fusion of Steinman's vertebrae did not take place, and that the system fully fulfilled its intended purpose.

1. Summary Judgment Standard

Rule 56 of the Federal Rules of Civil Procedure provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." A fact is "material" only if it "might affect the outcome of the suit under governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986). A "genuine" dispute exists "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." Id. In determining whether a genuine dispute regarding a material fact exists, the evidence and the inferences drawn from the evidence "must be viewed in the light most favorable to the party opposing the motion." Adickes v. S. H. Kress & Co., 398 U.S. 144, 158–59, 90 S. Ct.1598, 1609, 26 L. Ed. 2d 142 (1970) (internal quotations and citation omitted); see also Fed. R. Civ. P. 56(c).

"Only when reasonable minds could not differ as to the import of evidence is summary judgment proper." Bryant v. Maffucci, 923 F.2d 979, 982 (2d Cir. 1991) (citation omitted). Indeed, "[i]f, as to the issue on which summary judgment is sought, there is any evidence in the record from which a reasonable inference could be drawn in favor of the opposing party, summary judgment is improper." Sec. Ins. Co. of Hartford v. Old Dominion Freight Line, Inc., 391 F.3d 77, 82-83 (2d Cir. 2004) (citations omitted). The function of the court is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson, 477 U.S. at 249.

When the parties cross-move for summary judgment, "the standard is the same as that for individual motions for summary judgment." Natural Res. Def. Council v. Evans, 254 F.Supp.2d 434, 438 (S.D.N.Y. 2003). "The court must consider each motion independently

of the other and, when evaluating each, the court must consider the facts in the light most favorable to the non-moving party." Id. (citing Morales v. Quintel Entm't, Inc., 249 F.3d 115, 121 (2d Cir. 2001)).

2. Manufacturing Defect

Under New York law,[13] a "manufacturer who places a defective product on the market that causes injury may be liable for the ensuing injuries. A product may be defective when it contains a manufacturing flaw." Liriano v. Hobart Corp., 92 N.Y.2d 232, 237, 677 N.Y.S.2d 764, 700 N.E.2d 303 (1998). To recover damages for a manufacturing defect, a plaintiff must establish that the product was defective and that the defect was a substantial factor in causing the injury. Derienzo v. Trek Bicycle Corp., 376 F. Supp. 2d 537, 560 (S.D.N.Y. 2005).[14]

Steinman's claim rests on her assertion that the screws fractured too early, that is, they failed before reaching the amount of cycles recommended by the ASTM. The ASTM develops standards for various materials. Spinal Concepts identified "ASTM F1717-96" as the standard it used when testing the AcuFix system. (James Freid Deposition, pp. 45-51; Docket No. 68-13; Exhibit L.) The purpose of the standard is to determine the endurance limit of the plate and screws. To meet the standard, a specimen (in this case, the AcuFix system) must be able to survive 5,000,000 cycles before fracturing. (Parrington Declaration ¶ 45.) Based on his tests, Parrington approximated that the screws failed at approximately

[13] In this diversity action, New York law governs all issues presented by the motions for summary judgment. McCarthy v. Olin Corp., 119 F.3d 148, 153 (2d Cir.1997) (applying New York law to products liability action against out-of-state defendants).

[14] There is no dispute that the product was being used for the purpose, and in the manner, normally intended. See Codling v. Pagila, 32 N.Y.2d 330, 342, 345 N.Y.S.2d 461, 298 N.E.2d 622 (1973).

105,000 cycles, well below the 5,000,000 ASTM standard. (Parrington Declaration ¶¶ 41,42,46,50.) Thus, Steinman asserts, the AcuFix system was defective because it did not meet the industry standard.

Spinal Concepts, however, argues the ASTM standard is not an industry performance standard and is merely a test standard (a fact Parrington admits). Therefore, it continues, the standard cannot be used as basis for liability. They further argue that the AcuFix system fully achieved its intended purpose. Spinal Concepts explains that the AcuFix system is intended to assist healing only in the limited period between surgery and bone fusion. Marta Villarraga, Ph.D. and William Kane, Ph.D., Spinal Concepts' expert witnesses, opine that the AcuFix system fractured because of incomplete fusion, causing the screws to bear the full load of the stresses, which is contrary to its intended use. (Villarraga and Kane Report p. 6; Docket No. 47-7.)

Spinal Concepts also points out the following set of facts: Steinman had her surgery on May 3, 2002. According to ASTM F1717-96, the very standard referred to by Parrington and relied on by Steinman, an implant might undergo 7,000 stresses per day in the human body. On August 5, 2002, X-rays revealed that the screws were intact. At 7,000 per day, that amounts to 658,000 cycles without fracture. As Spinal Concepts notes, this is incompatible with Parrington's finding that the screws failed after just 105,000 cycles.

As an initial matter, however, neither party can definitively assess the number of the cycles that the screws withstood while implanted in Steinman's spine. Each party comes to its own, imprecise, conclusion. Spinal Concepts relies on an estimate by the ASTM, while Steinman relies on her expert's own estimate. Thus, a genuine dispute exists, and, based on the evidence presented, it is the fact-finder's duty to reach its own determination.

Further, even if this matter were settled, compliance or non-compliance with the ASTM standard is not dispositive. It is the fact-finder's task to determine whether Steinman's reliance on the ASTM standard is appropriate. See Rupolo v. Oshkosh Truck Corp., 749 F. Supp 2d 31, 43 (E.D.N.Y. 2010) (applying this rule to standards developed by the American National Standards Institute).

Moreover, the question still remains as to whether the screws should have failed after, at most, six months of use. Dr. Capicotto testified that Steinman was healing well in the months immediately following her surgery. Then, rather abruptly, she was not. This may be because, as Spinal Concepts and its experts assert, Steinman's vertebrae did not fuse properly, diverting more pressure to the screws than they were intended to handle and causing them to fracture. But it may also be because the screws were manufactured deficiently and broke before they should have. More to the point, it is the fact-finder's domain to determine if fusion would have occurred if not for the broken screws (or, on the other hand, if the screws outlived their intended purpose and only broke because fusion took too long). See 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2729.1, at 577 (3d ed.1998) (noting that, by their very nature, products liability cases are rarely appropriate for summary judgment).

"Where a defendant raises alternative causes to avoid liability for a product's failure, a plaintiff 'raise[s] a triable question of fact by offering competent evidence which, if credited by the jury, [i]s sufficient to rebut defendant['s] alternative cause evidence.'" Quinlan v. Stryker Corp., No. 09 Civ. 7284, 2010 WL 3291807, at *1 (S.D.N.Y. Aug. 12, 2010) (quoting Ramos v. Howard Indus., Inc., 10 N.Y.3d 218, 224, 855 N.Y.S.2d 412, 885 N.E.2d 176 (2008)); see also Lynch v. Trek Bicycle Corp., No. 01 Civ. 3651, 2011 WL

1327032, at *3 (S.D.N.Y. Mar. 30, 2011). Here, Steinman's evidence – that the screws failed prematurely after only 105,000 cycles, before bone fusion could take place, and before reaching the ASTM standard – could be credited by a reasonable jury.[15] Consequently, with respect to Steinman's manufacturing defect claim, both party's motions for summary judgment are denied.[16]

3. Design Defect

To establish a prima facie case in strict products liability for design defects under New York law, "the plaintiff must show that the manufacturer . . . marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury." Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 107, 463 N.Y.S.2d 398, 450 N.E.2d 204 (1983). The plaintiff bears the burden of establishing "that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm *and it was feasible to design the product in a safer manner*." Id. (emphasis added); see also Fane v. Zimmer, Inc., 927 F.2d 124, 128 (2d Cir. 1991) (citing Voss, 59 N.Y.2d at 108); Clinton v. Brown & Williamson Holdings, Inc., 498 F.Supp.2d 639, 646 (S.D.N.Y.2007) (explaining that the plaintiff must put forth "proof of a feasible alternative design [as] a prerequisite to establish a prima facie design defect claim under New York law"); Liz v. William Zinsser & Co., 253 A.D.2d 413, 414, 676 N.Y.S.2d 619 (2d Dep't 1998) ("Finally, the court erred in not dismissing those causes of action predicated

[15]Steinman has also raised a genuine dispute that the AcuFix system was a substantial factor in causing her injury. Dr. Capicotto, by declaration, states that he believes Steinman suffered "an aggravation of her previous injuries as a result of the fracture of the Spinal Concepts' AcuFix screws." (Capicotto Declaration ¶ 35; Docket No. 69.)

[16]Because Steinman's breach of warranty claim is tied to her manufacturing defect claim, those motions for summary judgment are also denied.

on a design defect theory, as the plaintiffs failed to demonstrate that it was feasible to design the product in a safer manner.")

Parrington repeatedly admits in his deposition that he is not an expert in biomedical engineering. (See, e.g., Parrington Declaration, p. 109.) Parrington states, "My area of expertise was to determine and characterize the failure of the screws, not to . . . understand the surgical use of the device." (Id. p. 103.) Parrington also admits he has performed no research regarding other types of screws that could be used for the type of procedure in question. (Id. p. 114.) Although he is qualified to analyze the reasons for the screw's failure, he, admittedly, is not in a position to offer potentially better designs. Nor does he attempt such a proposal. Further, Steinman does not offer any other expert witness in this regard.

Therefore, with no evidence of a feasible, alternative design, Steinman is unable to make out a prima facie case in strict products liability for design defect. See Guarascio v. Drake Assoc. Inc., 582 F. Supp. 2d 459, 463 (S.D.N.Y. 2008) ("New York courts uniformly rule that competent, non-conclusory expert testimony is needed in cases involving more complex design issues." (collecting cases)); see also Donovan v. Centerpulse Spine-Tech, Inc., No. 03 Civ. 0376, 2010 WL 126975, at *7, n.6 (W.D.N.Y. Mar. 31, 2010) (granting summary judgment for defendants where the plaintiff claimed that a similar medical device failed before reaching the ASTM standard, because, in part, the plaintiff failed to offer evidence of a feasible, safer design alternative). Accordingly, Spinal Concepts' motion for summary judgment as to Steinman's design defect claim is granted. Further, because the analysis under strict liability and negligent design defect is identical, Spinal Concepts' motion with respect to Steinman's negligent design claim is also granted. See Searle v.

Suburban Propane Div. of Quantum Chem. Corp., 263 A.D.2d 335, 700 N.Y.S.2d 588, 591 (3d Dep't 2000) ("[I]n a design defect case, there is almost no difference between a prima facie case in negligence and one in strict liability."); see also See Colon ex rel Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001) ("For the purposes of analyzing a design defect claim, the theories of strict liability and negligence are virtually identical.")

4. Failure to Warn

It is well settled with respect to prescription drugs and medical devices that a manufacturer's duty to warn is owed not the patient, but to the treating physician as the "learned intermediary." Bravman v. Baxter Healthcare Corp., 984 F.2d 61 (2d. Cir. 1993); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87 (2d. Cir. 1980).

When a user is fully aware of the nature of the product and its dangers, the supplier cannot be held liable for failure to warn. Billar v. Minnesota Min. And Mfg. Co., 623, F.2d 240, 243 (2d Cir. 1980) (citing Rosebrock v. General Electric Co., 236 N.Y. 227, 236, 140 N.E. 571 (1923). The rationale for this rule is that knowledge of the danger is equivalent to prior notice; no one needs notice of that which he already knows. Borowicz v. Chicago Mastic Co., 367 F.2d 751, 758 (7th Cir. 1966) (applying New York law). The plaintiff must have "actual knowledge" of the "specific hazard" that caused the injury. Liriano, 92 N.Y.2d at 241. Although this rule was developed in the context of a sophisticated professional using the tool of his trade (e.g., a carpenter using a saw), the force of its logic is equally applicable here.

Dr. Capicotto admits that he knew that the screws could potentially break. (Capicotto Deposition, p. 48.) He had used similar products before and discussed with Steinman the possibility that the hardware could fracture or become dislodged. (Id. pp. 33-34, 48-50.)

Although Dr. Capicotto cannot recall getting the product insert, which contains warnings and information about the product, he had reviewed similar product inserts and was aware of all the "precautions" and "possible adverse effects" of the AcuFix system contained in the insert. (Id. pp. 48-49, 61-64, 66.) Namely, that the implant could break, migrate in the body, or loosen. (Id.) The evidence is clear that Dr. Capicotto, as the learned intermediary, was fully aware of the nature of the product and the "specific hazards" that the product presented.

Even assuming, *arguendo*, that Spinal Concepts did fail to adequately warn Dr. Capicotto, Steinman presents no evidence that any such failure caused her injuries. See Bravman, 984 F.2d at 75 ("A plaintiff proceeding under a failure-to-warn theory in New York must demonstrate that the failure to warn adequately of the dangers of a product was a proximate cause of his or her injuries.") Therefore, Spinal Concepts' motion for summary judgment regarding this claim is granted. See Liriano, 92 N.Y.2d at 241.

IV. CONCLUSION

For the foregoing reasons, Spinal Concepts' motion to exclude Dr. William Capicotto's and Ronald Parrington's testimony is denied, while its motion for summary judgment is granted in part and denied in part. Further, Steinman's motion for summary judgment is denied.[17]

[17]Neither party has addressed Richard Steinman's claim for loss of consortium, and this Court declines to grant summary judgment to either party concerning that claim.

V. ORDERS

IT HEREBY IS ORDERED, Defendant's Motion in Limine to Exclude the Testimony of Dr. William Capicotto and Ronald Parrington (Docket No. 72) is DENIED.

FURTHER, Defendant's Motion for Summary Judgment (Docket No. 46) is GRANTED in part and DENIED in part.

FURTHER, Plaintiffs' Motion for Summary Judgment (Docket No. 64) is DENIED.

SO ORDERED.

Dated: September 22, 2011
Buffalo, New York

/s/William M. Skretny
WILLIAM M. SKRETNY
Chief Judge
United States District Court